

Legal framework for the marketing of food insects in the European Union

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Abstract

This article provides an overview of the current legal situation concerning the marketing of food insects in the European Union. It also details how this issue can be expected to be handled in the future. For this article, a study of the current legislation was carried out and the competent authorities in European member states and in the individual German federal states were surveyed. Since Regulation (EU) 2015/2283 became completely valid on 1 January 2018 and since the authorization requirement became applicable on the same date, different countries within the European Union have interpreted the transitional provisions of Article 35 (2) of the regulation differently. This has resulted in differences in the species of insects that are allowed to continue to be marketed in the various countries until a decision is made regarding the applications concerning those species for authorization as novel foods or regarding notification about them as traditional foods from third countries.

Keywords: Food insects, entomophagy, European Union, marketing

This article outlines the current legal conditions for the market-

ing of food insects in the European Union as of 7 October 2019

 (date of acceptance of the article). Any new legal developments that have taken place since that date are not taken into account in the article.

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Introduction

Recently, there has been increasing discussion around the topic of "insects as food" in the European Union (EU). Obstacles standing in the way of the consumption of food insects include not only consumer hesitancy, but also legal uncertainty. Prior to 1 January 2018, there was no consistent legal framework dealing with food insects in the EU.

Although Regulation (EC) No 258/97 on novel foods and novel food ingredients (IIII) List of Legislative Requirements) was in force until 31 December 2017, it was not applicable to whole insects, parts of insects or ingredients derived from insects (e.g. insect flour), as it only applied to food ingredients isolated from animals (e.g. insect extracts). Therefore, they were able to be marketed without authorization (Regulation (EC) No 258/97 Art. 1 [2] e).

Whole insects, insect parts and ingredients derived from insects were specifically included in the legal framework for the first time in Regulation (EU) 2015/2283 on novel foods, which has been fully valid since 1 January 2018.

Material and methods

In addition to the incorporation of EU legislation, from February to March 2019, inquiries were sent by e-mail to the competent authorities for food monitoring in all EU member states as well as those in the individual German federal states [1, 2].

In these e-mails, the competent authorities were asked how the issue of food insects is currently being handled and whether there had been any changes in the country in question following the deadline for applications for authorization as novel food or notification of traditional food according to the transitional provision of Article 35 (2) of Regulation (EU) 2015/2283. If there was no response, the in-

Name	Applicant	Specification	Conditions of use
1. House cricket (Acheta domesticus)	Belgian Insect Industry Federation (BiiF), Belgium	adult, heat-treated	whole animals ^h ; dried ^h ; powder ^h ; pastes ^{h,j} ; noodles/pasta ^{d,i} ; protein products ^{(j,j,l} ; confectionery ^{(j,j} ; bakery wares ^{g,i} ; salads, savoury based sand- wich spreads ^{f,j} ; nut spreads ^{f,j} ; ready-to-eat savouries, snacks ^h
	Fair Insects BV (A Protix Company), The Netherlands	whole/ground (heat-treated/frozen/ freeze-dried)	Cereals/cereal-like flours; bread and similar products; breakfast cereals; fine bakery wares; pasta, dough and similar products; spices; fish and seafood processed; dishes, incl. ready to eat meals; food for particular diet; sausages; meat imitates; soups, salads; mixed/alcoholic beverages, beer/ beer-like beverages, unsweetened spirits, liqueurs; confectionery incl. choc- olate; processed/preserved vegetables; vegetables/vegetable products; nut/ seed pastes/emulsions/mass, cream cheese; snacks (excl. chips); processed, whole meat products
2. Lesser mealworm (Alphitobius diaperinus)	Proti-Farm Holding NV, The Netherlands	larvae; blanched/ frozen/ground/dried or freeze-dried	Cereals/breakfast cereals or bars; dough products or noodles/pasta; bread; rolls; fine bakery wares; processed meat; soups, broths; sauces; snacks con- taining potato/cereals/flour/starch; dried snacks; supplements; meat imitates; chocolate, chocolate products; protein topping
3. Honey bee drone brood (Apis mellifera)	Finnish Beekeepers' Association, Finland	pupae	whole or as an ingredient in other foods
4. Tropical house cricket (Gryllodes sig- illatus)	SAS EAP Group - MICRONUTIS, France	dried (whole/ground)	Bread products ^a ; baked products ^a ; breakfast cereals; pre-packaged (whole); cereal bars ^a ; biscuits, crackers, cookies ^a ; chocolate confectionery ^a ; sweeteners ^a ; salad dressings ^a ; ready-to-eat meals ^a ; noodles/pasta ^a
5. Black soldier fly (Hermetia illucens)	Enorm Biofactory A/S, Denmark	larvae; dried, ground	Bakery wares ^a ; snacks containing potato/cereals/flour/starch ^a
6. European migratory locust <i>(Locusta migratoria)</i>	Belgian Insect Industry Federation (BiiF), Belgium	nymph, adult; heat-treated	Protein products ¹ ; flour; confectionery; salads and savoury sandwich spreads; baked goods; ready-to-eat savouries, snacks; nut spreads; soups, broths; sauces
	Fair Insects BV (A Protix Company), The Netherlands	adult; whole/ground (heat-treated/frozen/ freeze-dried)	Cereals/cereal-like flours; bread and similar products; breakfast cereals; fine bakery wares; pasta, dough and similar products; spices; fish and seafood processed; dishes, incl. ready to eat meals; food for particular diet; sausages; meat imitates; soups, salads; mixed/alcoholic beverages, beer/beer-like bever- ages, unsweetened spirits, liqueurs; confectionery incl. chocolate; processed/ preserved vegetables; vegetables/vegetable products; nut/seed pastes/ emulsions/mass, cream cheese; snacks (excl. chips); processed, whole meat products
7. Mealworm (Tenebrio molitor)	Belgian Insect Industry Federation (BiiF), Belgium	larvae; heat-treated	whole ^h ; dried ^h ; flour ^h ; sterilized ^h ; dough ^{h,j} ; roasted ^h ; canned ^{h,k} ; flour/other milled products, starch ^{e,i} ; noodles/pasta ^{e,i} ; protein products ^{e,j,j} ; confection- ery ^{a,i} ; salads and savoury based sandwich spreads ^{b,j} ; bakery wares ^{g,j} ; nut spreads ^{a,j} ; soups, broths ^{c,i} ; sauces ^{e,j} ; ready-to-eat savouries, snacks ^{e,j}
	<i>Fair Insects BV,</i> The Netherlands	larvae; whole/ ground (heat- treated/frozen/ freeze-dried)	Cereals/cereal-like flours; bread and similar products; breakfast cereals; fine bakery wares; pasta, dough and similar products; spices; fish and seafood processed; dishes incl. ready to eat meals; food for particular diet; sausages; meat imitates; soups, salads; mixed/alcoholic beverages, beer/beer-like bever- ages, unsweetened spirits, liqueurs; confectionery incl. chocolate; processed/ preserved vegetables; vegetables/vegetable products; nut/seed pastes/ emulsions/mass, cream cheese; snacks (excl. chips); processed, whole meat products; roasted/extruded cereal products, seed/root based products
	SAS EAP Group - MI- CRONUTIS, France	dried (whole/ground)	Bread products ^a ; baked products ^a ; breakfast cereals; pre-packaged (whole); cereal bars ^a ; biscuits, crackers, cookies ^a ; chocolate confectionery ^a ; sweeteners ^a ; salad dressings ^a ; ready-to-eat meals ^a ; noodles/pasta ^a

Table 1: Summary of the contents of the applications for authorization of food insects as novel foods (last updated: 4 October 2019) [3]

^a = 10%, ^b = 20%, ^c = 25%, ^d = 40%, ^e = 50%, ^f = 70%, ^g = 80%, ^h = 100% of the species; ⁱ = dried, ^j = fresh, ^k = drained;

¹ = excluding dairy analogues

formation provided on the websites of the competent authorities was used where available.

Food regulatory aspects

Novel food regulation

According to Regulation (EU) 2015/2283, food insects fall into the category of "food consisting of, isolated from or produced from animals or their parts [...]" and can only be marketed after receiving marketing approval (Regulation (EU) 2015/2283 Art. 3 [2] a v, Art. 6 [2]). All authorized novel foods are included by the European Commission (COM) in a Union list which did not contain any insect species until 4 October 2019 (Commission Implementing Regulation (EU) 2017/2470). In order for an applicant to obtain an authorization for an insect species as a novel food, they must submit an application to the COM in accordance with Article 10 et seq. of Regulation (EU) 2015/2283. After the validity of this application has been checked, it is then made



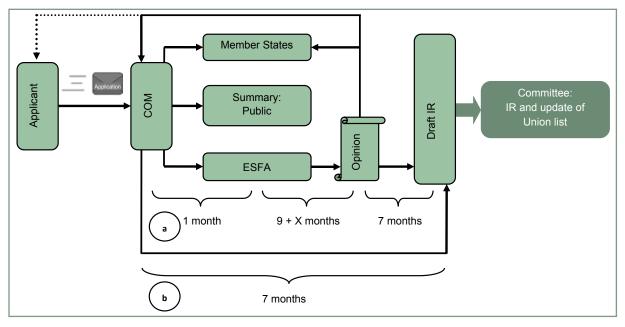


Fig. 1: Diagram showing the approval procedure for novel foods (Regulation 2015/2283 Art. 10 et seq.) ^a = approval procedure with EFSA opinion; ^b = approval procedure without EFSA opinion COM = European Commission; IR = implementing regulation; EFSA = European Food Safety Authority

available to the Member States and a summary is published on the COM website (if the applicant has not requested confidentiality in accordance with Article 23 of Regulation (EU) 2015/2283).

On 4 October 2019, 11 out of 20 applications for insect species were already available there (\bullet Table 1) [3, 4]. The COM then has 7 months to either forward an implementing act to the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) or seek an opinion from the European Food Safety Authority (EFSA) regarding the safety of the food. If an opinion is requested from the EFSA, they must provide one within 9 months. This deadline can be extended if additional information is required from the applicant ("9 + x months").

The COM then draws up an implementing act based on the opinion. Other food business can then bring this food to market as an approved use of the food without having to apply for a new marketing approval (Regulation (EU) 2015/2283 Art. 10 et seq.; • Figure 1).

Food insects can also be marketed as traditional foods from third countries. A notification must be submitted to the COM for this. The notification must include the country of origin and proof of the food's history of use as a safe food. If no objections are raised by the Member States or the EFSA within 4 months, the COM issues marketing approval and the food is included in the Union list. If there are justified objections regarding the safety of the traditional food, the applicant still has the option of submitting an application to the COM to register the food as a novel food in accordance with Article 16 of Regulation (EU) 2015/2283. In contrast to the authorization process described above, the EFSA has only 6 months to issue an opinion in this case, and a draft implementing regulation based on the opinion must be submitted to the COM within 3 months. This process can also take longer if additional information is required from the applicant ("6 + x months"). On the date in question (4 October 2019), five notifications regarding food insects as novel foods had already been submitted to the

COM, none of which had yet been published by the COM on their website (Regulation (EU) 2015/2283 Art. 14 et seq.; • Figure 2) [3, 4]. In accordance with Article 35 of Regulation (EU) 2015/2283, applications for authorization submitted within the scope of Regulation (EC) No 258/97 are treated as applications under the current regulation. In addition, foods that did not fall within the scope of Regulation (EC) No 258/97 but now fall within that of Regulation (EU) 2015/2283 and were lawfully on the market before 1 January 2018 may continue to be marketed until the decision on the application has been made. This only applies to the food insect species for which an application for authorization or a notification has been submitted by 1 January 2019, subject to compliance with the relevant specifications and conditions of use (Regulation (EU) 2015/2283 Art. 35; Commission Implementing Regulation (EU) 2017/2468 Art. 11; Commission Implementing Regulation (EU) 2017/2469 Art. 8 [5]).

Labeling and general hygiene regulations

Regulation (EC) No 178/2002 is the binding regulation for general legal classification of food insects. In addition to the general principles and requirements mentioned in this regulation, the regulation also stipulates that



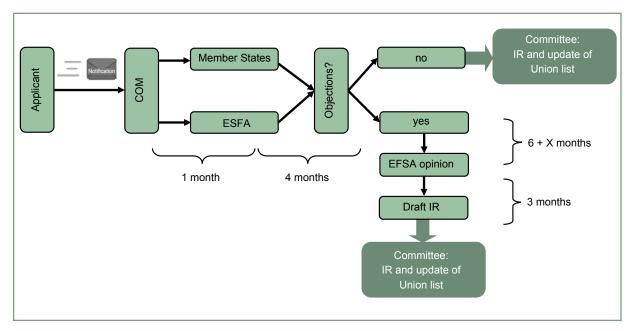


Fig. 2: Diagram showing the approval procedure for traditional foods from third countries as novel foods (Regulation 2015/2283 Art. 14 et seq.)

COM = European Commission; IR = implementing regulation; EFSA = European Food Safety Authority

insects that have been bred for the production of animal feed may not be used as food (Regulation (EC) No 178/2002 Art. 2 a).

The food business operator is always responsible for compliance with the contents of the regulation. The EFSA, which was established on the basis of Article 22 of Regulation (EC) No 178/2002 to provide scientific advice and analyze food safety risks, published a risk profile on 8 October 2015 in order to provide information on the production and consumption of insects. The risk profile includes biological, chemical and environmental hazards that can be expected to be associated with the consumption of insects [5]. With regard to labeling, there are currently no legally binding regulations that are specific to food insects or food insect products. Therefore, it is stipulated that at least the information listed in Article 9 (1) of Regulation (EU) No 1169/2011 on the provision of food information to consumers must be present on the label. In Germany, labeling is sometimes based on the Austrian guideline for bred insects used as food. Under this guideline, in addition to the name of the food, the general and scientific name of the species should be shown, along with an allergy warning (because insects contain substances-such as tropomyosin and arginine kinase-that can cause cross-reactions in people who are allergic to crustaceans or mites) [5, 6].

Additional regulations that apply include Regulation (EC) No 852/2004, which sets out general food hygiene rules for food business operators and Regulation (EC) No 853/2004, which sets out specific hygiene rules for food of animal origin. Since food insects fall under the definition of "products of animal origin" in Regulation (EC) No 853/2004, in addition to the provisions of Regulation (EC) No 852/2004, food business operators are obliged to comply with the requirements of Annexes II and III of Regulation (EC) No 853/2004, which currently (as of 4 October 2019) do not contain any explicit provisions for food insects or food insect products (Regulation 853/2004 Annex No. 8.1.). The COM therefore published a draft amendment regulation to include

insects in Annex III of Regulation (EC) No 853/2004 (Document Ares [2019] 382900). The draft amendment contains provisions for restricting authorized insect species and for regulation of feed substrates.

The criteria for *Listeria monocytogenes* from Regulation (EC) 2073/2005 on microbiological criteria (Regulation 2073/2005 Annex I Chapter 1 No. 1.1–1.3) must also be applied to food insects and food insect products. No other microbiological criteria have been established thus far, but some such criteria are discussed in national advisory guidelines on food insects [7].

In addition, on 2 February 2019, the International Platform of Insects for Food and Feed (IPIFF), which represents the interests of the insect production sector, published a draft EU guide on good hygiene practices for producers producing insects for food and feed purposes [8]. This guide is intended to support businesses in producing safe products and thus in applying the relevant EU legislation on food and feed products. It includes general recommendations for the hygiene requirements that should be applied in the breeding, processing and marketing of food insects.



Regulatory aspects regarding feed

Insects for human consumption can be fed as livestock with category 3 feeds, which are listed in Regulation (EC) No 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption. Exclusions include processed animal proteins from the same type of animal, catering waste and herbage from cultivated land (waiting period of at least 21 days) (Regulation (EC) No 1069/2009 Art. 3 No. 6 a, Art. 10, Art. 11 [1]).

In addition, according to Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, no animal protein may be fed to food insects (Regulation 999/2001 Art. 7 [2]). Nevertheless, feed materials and compound feed may be used to feed food insects if they are produced, marketed and used in accordance with the general conditions laid down in Chapter III and the specific conditions laid down in Chapter IV (sections A-C) of Regulation (EC) No 999/2001 (Annex IV Chapter II b).

According to the draft amendment to Annex III of Regulation (EC) No 853/2004, the feeding of insects with non-animal products and the following animal products is to be permitted in the future (Document Ares [2019] 382900):

• fishmeal

- Blood products from non-ruminants
- Di- and tricalcium phosphate of animal origin
- Hydrolysed proteins from non-ruminants
- Hydrolysed proteins from ruminant hides and skins
- Gelatine and collagen from non-ruminants
- Eggs and egg products
- Milk, milk-based products, milk-derived products, colostrum
- Honey
- Rendered fats

Regulatory aspects regarding transmissible animal diseases

Until the Regulation (EU) 2016/429 on transmissible animal diseases and amending and repealing certain acts in the area of animal health comes into full force on 21 April 2021, the content of Directive 97/78/EC may be used as a guideline for dead food insects and Directive 92/65/EEC may be used for live insects. To date, Directive 92/65/EEC only contains requirements for the Western honey bee (Apis mellifera). Therefore, when importing honey bee drone brood as food, it should be ensured that the origin is an area that is not subject to a ban due to malignant foulbrood and that there is no infestation with the small hive beetle (Aethina tumida) or the Tropilaelaps mite (Tropilaelaps spp.). In addition, a health certificate corresponding to the specimen in Annex E of this directive must accompany the imported material (Directive 92/65/EEC Art. 8, Annex A). From 21 April 2021 onwards, early detection, general monitoring and behavior in the event of an epidemic will be regulated by Regulation (EU) 2016/429 (Regulation (EU) 2016/429 Art. 1).

Regulatory aspects regarding animal welfare

The EU does not have legal competence to regulate animal welfare issues. The Treaty of Lisbon inserted Article 13 into the Treaty on the Functioning of the EU in 2009. Under this article, each Member State is responsible for general animal welfare issues (Art. 13 TFEU). In Germany, the applicable principle is that the life and well-being of animals must be protected and that no one may cause pain, suffering or harm to an animal without reasonable cause (Paragraph 1 Animal Welfare Act-Tierschutzgesetz [TierSchG]). However, the extent to which insects are capable of feeling pain, suffering and harm has not yet been sufficiently researched. Therefore, until it is proven that they cannot, it should be assumed from an animal welfare point of view that insects can experience pain, suffering and harm and should be treated accordingly [9].

Regulatory aspects regarding the environment

In accordance with Regulation (EU) No 1143/2014 on the prevention and management of the introduction and spread of invasive alien species, the COM has drawn up a list of species that may not be introduced into the EU, kept or bred there (Regulation (EU) No 1143/2014 Art. 7) [10]. Until 4 October 2019, the only insect species on this list was the Asian hornet (*Vespa velutina nigrithorax*), which is not relevant as a food insect.

The Annex to Regulation (EU) 2016/2031 on protective measures against pests of plants specifies criteria for classifying food insects as pests. Before starting to breed the insect species in question, it should be checked whether these criteria would be met if individual individuals escaped into the environment.

Official food monitoring

As of 14 December 2019, Regulation (EU) 2017/625 on official controls and other official activities is in full force. A delegated regulation was published by the COM on the requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption. This is to ensure that imported insects meet the requirements for food.



Application of Regulation (EU) 2015/2283	Countries		
1. Countries <i>without</i> advisory guidelines and <i>not</i> applying the transitional provi- sions ^a	Bulgaria, Estonia, France [11], Greece, Ireland, Italy [12], Croatia, Latvia, Lithuania [13], Luxembourg, Poland, Portugal, Romania, Sweden, Slovakia, Slovenia, Hungary, Cyprus		
2. Countries <i>with</i> advisory guidelines that <i>are</i> applying the transitional provisions ^a	Germany, The Netherlands, Spain [16], United Kingdom [17]		
3. Countries <i>with</i> advisory guidelines that <i>are</i> applying the transitional provisions	Belgium, Denmark, Finland, Austria		
4. No information	Malta, Czech Republic		
Table 2: Results of the survey on the application of the transitional provisions of Article 35 (2) of Regulation (EU) 2015/2283 on			

food insects / food insect products in the EU member states

^a where a source is cited, this is because there was no reply, so the information on the competent authority's website was referenced

Application of Regulation (EU) 2015/2283	German federal states
German federal states <i>with</i> advisory guidelines that <i>are</i> applying the transi- tional provisions ^a	Baden-Württemberg, Bavaria [14], Brandenburg, Bremen, Hamburg, Hesse, Mecklenburg-Western Pomerania, Lower Saxony, Saxony-Anhalt, Schleswig-Hol- stein, Thuringia
No information	Berlin, Rhineland-Palatinate, Saarland, Saxony

Table 3: Results of the survey on the application of the transitional provisions of Article 35 (2) of Regulation (EU)2015/2283 on

food insects / food insect products in Germany

^a where a source is cited, this is because there was no reply, so the information on the competent authority's website was referenced

The term "insects" is used to mean foodstuffs "[...] food consisting of, isolated from or produced from insects or their parts including any life stadia of insects intended for human consumption [...]" (Regulation (EU) 2019/625 Art. 2 No. 17). Third countries or parts of third countries from which the entry of insects into the Union is authorized may in future be determined using Article 20 of Commission Implementing Regulation (EU) 2019/626.

In addition, Commission Implementing Regulation (EU) 2019/628 concerning model official certificates for certain animals and goods has been published. Such a model is contained in Part XIII of Annex II to Commission Implementing Regulation (EU) 2019/628 in the form of a certificate for the marketing of food insects in the Union.

Handling of the legislation in EU member states

Eighteen of the 28 member states of the EU reject the application of the transitional provision of Article 35 (2) of Regulation (EU) 2015/2283 and allow the marketing of food insects only after they are included in the Union list (• Table 2, No. 1). The main objective of this is to ensure consumer safety, by first carefully checking the risk analyses

included in the applications for authorization as novel a food or, in the case of notification as traditional food, checking the demonstration of safety.

In other Member States, the transitional provisions will be applied if the generally applicable legislation is complied with. Species for which an application for authorization as a novel food or a notification of a traditional food from a third country has been submitted by 1 January 2019 are allowed to continue to be marketed until a decision on their application is made, but this can only continue until 2 January 2020 at the latest (• Table 2, No. 2).

Some countries have some special features in this regard. For example, in **Germany**, the respective authorities of the individual Länder (federal states) are responsible for applying the transitional provisions of Article 35 (2) of Regulation (EU) 2015/2283 due to federalism. Although this could in theory lead to different regulations within the individual Länder, the competent Länder authorities take the same view on the subject as mentioned in paragraph 2 (• Table 3).

Another country-specific special feature was the information on food insects published by the **Netherlands** Food and Consumer Product Safety Authority (NVWA), which, among other things, mentions agreements with VENIK (Dutch Insect Breeders' Association) on marketing (e.g. agreements on heating-through and allergen information) [15].

In addition, in October 2018, the **Spanish** Ministry of Health, Consumer Affairs and Social Welfare published a statement on the current situation with regard to insects in human nutrition in collaboration with the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) [16]. The statement contains a list of insect species that fell within the scope of the transitional provisions of Regulation (EU) 2015/2283 in other EU countries. Until 1 January 2019, these insects could also be marketed in





Fig. 3: Food insect product groups investigated at the Chemical and Veterinary Investigation Office Freiburg (CVUA) (last updated: 4. October 2019) from left to right: whole insects, burger patties, ready-to-eat meals, granola, noodles/pasta, bars

Spain. Since 1 January 2019, only those species for which an application for authorization or a notification has been submitted by that date are allowed to be marketed.

There are also countries in which national advisory guidelines have been published to facilitate the management of food insects and to specify the conditions for applying the transitional provisions of Article 35 (2) of Regulation (EU) 2015/2283 (• Table 2, No. 3). These differ in their content—for instance there are differences with regard to the microbiological criteria for food insects or food insect products and the species that are allowed to be marketed in the individual countries. Grabowski et al. [7] have already carried out a detailed evaluation and comparison of the guidelines. The most important aspects of the marketing of food insects are summarized again below, taking into account the current data as of 4 October 2019.

In **Belgium**, a circular on the breeding and marketing of insects and insect-based foods for human consumption was published by the Federal Agency for the Safety of the Food Chain (FASFC) in 2014 and it was updated on 5 November 2018 [18]. Furthermore, on 1 January 2018, the Belgian Federal Public Service published an information

letter about the current status of the commercialization of insects or insect-based products for human consumption on the Belgian market after 1 January 2018 [19]. From that date until the issuance of approval, only the following three species, for which Belgian applications for approval have been submitted by that date, are allowed to be marketed (\bullet Table 1):

- House cricket (Acheta domesticus)
- European migratory locust (*Locusta migra-toria*)
- Mealworm (Tenebrio molitor)

Another document was published in **Denmark** in 2015 by the Danish Ministry of Environment and Food with the title: "Insects — farming and use as feed and food in Denmark and the EU — what's allowed and what is not?"—last updated on 22 February 2019 [20]. The following whole insects may therefore continue to be marketed in Denmark until



a decision has been made on the applications concerning them:

- Mealworm (Tenebrio molitor)
- European migratory locust (*Locusta migra-toria*)
- Tropical house cricket (Gryllodes sigillatus)
- House cricket (Acheta domesticus)
- Lesser mealworm (Alphitobius diaperinus)
- Black soldier fly (Hermetia illucens)

In September 2017, the **Finnish** Food Safety Authority (Evira) changed the interpretation of Regulation (EC) No 258/97 so that whole insects fall within the scope of Regulation (EU) 2015/2283. Subsequently, they published a guideline on food insects and updated it in 2018 [21]. From 1 January 2019 onwards, only species for which an application for authorization has been submitted by that date may be marketed in Finland. These species are [22]:

- House cricket (Acheta domesticus)
- Lesser mealworm (Alphitobius diaperinus)
- Western honey bee (Apis mellifera)
- Tropical house cricket (Gryllodes sigillatus)
- Black soldier fly (Hermetia illucens)
- European migratory locust (*Locusta migra-toria*)
- Desert locust (Schistocerca gregaria)
- Mealworm (Tenebrio molitor)

The "Guideline for bred insects as food", published in **Austria** in 2017, is another example of existing regulations governing marketing, food safety and monitoring of food insects or food insect products [6]. The guideline contains some aspects that go beyond the EU legal provisions—aspects that in the absence of other requirements, are of particular relevance at present. Austria takes the view that processed insects already fall under the definition of Regulation (EC) No 258/97 and may only be marketed after approval. Therefore, the transitional provision of Article 35 (2) of Regulation (EU) 2015/2283 only applies to whole insects.

Discussion

The results of the research into the current legal situation with regard to the marketing of food insects in the EU show that the legal frame-work for marketing food insects is not yet comparable to that of food of other categories. Currently, many food insects and food insect products are already available on the European market (• Figure 3). These products have thus

far been marketed in the countries applying the transitional provisions of Article 35 (2) of Regulation (EU) 2015/2283 without the EFSA having issued an opinion on their safety. At present, only the food business operator ensures that these products do not pose a risk to consumers (Regulation (EC) No 178/2002 Art. 17 [1]).

It is therefore clear that the legal provisions require some adjustment. The following points, which have been unclear so far, will need to be taken into account when carrying out this adjustment:

• Labeling

Although it has been demonstrated that insects can trigger cross-reactions in people who are allergic to crustaceans or mites, to date there are no legal provisions requiring specific allergy warnings for food insects [5].

General hygiene regulations

In addition to the requirements for testing for *Listeria monocy-togenes* that have already been put in place, other testing targets will also have to be defined and enshrined in law. Thus far, only the recommendations given in previous publications have been used as the basis for the analysis of food insects and food insect products [5, 6, 18, 20, 21].

Regulatory aspects regarding transmissible animal diseases

It needs to be clarified whether transmissible animal diseases that could have an impact on animal health or public health (zoonoses) can occur on food insect farms.

• Regulatory aspects regarding animal welfare

The basic principles of the Animal Welfare Act should be implemented once it has been clarified whether insects can experience pain, suffering or harm, and regulations on the handling and slaughter of food insects should be established.

• **Regulatory aspects regarding the environment** Because breeding food insects can result in individuals escaping into the environment, there is a need for clarification about the extent to which alien species could have an impact on the environment.

The only legal area in which food insects have so far been included in legislation concerns official food monitoring and regulates the importation of food insects (Commission Delegated Regulation (EU) 2019/625; Commission Implementing Regulation (EU) 2019/626; Commission Implementing Regulation (EU) 2019/628). The planned inclusion of food insects in Annex III of Regulation (EC) No 853/2004 and the resulting regulation of feed substrates for food insects provides an indication of the direction further legal developments will take. Nevertheless, there is still a lack of comprehensive studies on the actual hazards that could be food insects and food insect products may pose.

The aim of establishing food insects and food insect products on the European market should always be to guarantee a safe food comparable to other product groups.

Outlook

Until insect species are approved as novel foods or the notification process for them as traditional foods from third countries is complete, the countries of the EU will continue to interpret the transitional provisions of Article 35 (2) of Regulation (EU) 2015/2283 differently. In addition to the countries are not allowing food insects to be marketed until that date, there are differences in the countries that apply the transitional provisions with regard to the species that may be marketed starting from 1 January 2019. For example, Finland allows the marketing of desert locusts (*Schistocerca gregaria*). This species was not among the applications that the COM published as being processed as of 4 October 2019. Consequently, it must be assumed that the application for this species was submitted by 1 January 2019. Publication can be expected after it has been checked and found valid.

At present (4 October 2019), only three of the eleven applications for authorization concerning insect species as novel foods that have been published on the COM website have been submitted by the COM to EFSA for evaluation. These are the following applications [4]:

- Lesser mealworm (*Alphitobius diaperinus*) from Proti-Farm Holding NV (• Table 1, No. 2)
- Tropical house cricket (*Gryllodes sigillatus*) from SAS EAP Group – MICRONUTIS (• Table 1, No. 4)
- Mealworm (*Tenebrio molitor*) from SAS EAP Group MICRONU-TIS (• Table 1, No. 7 c).

All other applications that have been submitted to date are yet to pass the completeness and eligibility checks. Therefore, given that the amount of time required for the approval procedure for novel foods is 17 months if an EFSA opinion is required (• Figure 1), the first approvals of insect species as novel foods cannot be expected to be issued before 1 January 2020. In the countries applying the transitional provisions of Article 35 (2) of Regulation (EU) 2015/2283, these species can be marketed until a decision has been reached on the applications concerning them. A maximum period of time for the processing of applications is yet to be established, meaning that the date until which transitional provisions can be applied has not yet been established either (Regulation (EU) 2015/2283 Art. 35 [2]).

Conclusion

Many of the laws generally applicable to animals are not applicable to insects because they are invertebrates. Compliance with the requirements contained in each country's guidelines is voluntary. As a result, many aspects of breeding, marketing and control of food insects are not covered by legislation.

Since the first approvals for insect species are expected in 2020 and since from that date onwards, these species will also be able to be marketed in the EU countries that have decided not to apply the transitional provisions of Article 35 (2), a revision of EU legislation should be carried out by that date. This could be done for instance through the publication of voluntary standards and legal frameworks to ensure the safety of food insects and food insect products.



Conflict of Interest

The authors declare no conflict of interest.

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